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Dose-response impact of a soluble fiber, NUTRIOSE®, on energy intake, body weight and body fat in humans

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Abstract

Background: Results from observational and intervention studies have shown that increased fiber intakes from different origins were related to positively impact weight management. The hypothesis is that a non-viscous soluble dietary fiber may influence anthropometric parameters and caloric intakes.

Methods: This 9-week randomized, double-blind, parallel clinical study in 100 overweight adults in China, investigated the effect of different dosages of dietary supplementation with a soluble non-viscous fiber, NUTRIOSE® on caloric intake, body weight, BMI and body fat. NUTRIOSE® is a glucose polymer resistant to digestion in the small intestine and largely fermented in the colon due to the presence of specific linkages. Subjects were randomized by body mass index and caloric intake, and then assigned to receive either placebo (orange juice) or 8 g, 14 g, 18 g, or 24 g/day of NUTRIOSE® mixed with orange juice (n=20 volunteers/group). Study products were orally consumed twice daily, three hours after breakfast (at 10 AM) and four hours after lunch (at 4 PM). Energy intake was assessed daily and anthropometric parameters were measured weekly.

Results: In a comparison of time effects within the same treatment group, the NUTRIOSE® groups ate significantly fewer kcal at subsequent meals with differences noted as early as 2 weeks for the 24 g group up to a reduction of 394 kcal/day and as early as 4 weeks for the 14g and 18g groups. Body weight and BMI decreased significantly in the 14, 18, and 24 g groups. Body fat decreased significantly in the 18 and 24 g groups.

Conclusions: These results demonstrate that a supplementation for 9 weeks with NUTRIOSE® significantly reduces energy intake, mean body weight, BMI, and body fat with a dose-response relationship.

Keywords: Dietary fiber, dextrin, energy intake, body weight, body fat, body mass index

Introduction

Overweight and obesity have reached epidemic levels and are associated with a cluster of metabolic disorders such as type 2 diabetes, metabolic syndrome, dyslipidemia, hypertension and osteoarthritis. Population consuming diets high in dietary fiber have a lower incidence of these chronic diseases [1]. High intake of dietary fiber is thought to support the regulation of energy intake and satiety, making it useful in weight management. Reports suggest that people who eat more fiber often have lower body weight than people who eat less fiber [2]. Numerous studies have examined not only body weight, but also body composition [3]. In cross-sectional observational studies, fiber intake is inversely associated with body weight [4] and body fat [5]. The Seven Countries Study demonstrated a significant inverse association between dietary fiber intake and subscapular skinfold thickness [6]. In a longitudinal study among young adults, fiber intake was inversely associated with body mass index (BMI kg/m^2) at all levels of fat intake after adjustment for lifestyle and other confounding factors [7]. More recently, Tucker and Thomas [8] also found that increasing dietary fiber reduces the risk of weight and fat gain in women, independent of several potential confounders, including physical activity. A systematic review by the American Dietetic Association on the health implications of dietary fiber [9,10] shows that high-fiber diets provide bulk, are satiating, and have been linked to lower body weight [10]. Three recent prospective studies and two cross-sectional studies provide additional support for the role of dietary fiber in obesity prevention. Du *et al.,* [11] followed a large cohort for 6.5 years and found that total fiber and cereal fiber were inversely associated with subsequent increases in weight and waist circumference. Likewise, a 20-month prospective cohort study (n=252) found that for each 1g increase in total fiber consumed, weight decreased by 0.25 kg and percent body fat decreased by 0.25 percentage points [8]. Similarly, a longitudinal study of dietary fiber intake (3g/1000 kcal) in Latino adolescents decreased their visceral adipose tissue (VAT) [12].

NUTRIOSE® is a purified resistant dextrin, a glucose polymer processed from wheat or corn starch and is considered as a dietary fiber [13-15]. In a first study, NUTRIOSE® supplementation for 12 weeks has demonstrated positive effects on body composition, energy intake and hunger in overweight men at a dosage of 34g/day [16]. A second study has been implemented in order to adapt the dosage of NUTRIOSE® to the dietary fiber recommendations. The primary and secondary objectives of this

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study were to assess satiety, to evaluate caloric intake and to measure anthropometric parameters in healthy overweight adult factory workers in China. NUTRIOSE® has induced a dose-dependant beneficial impact on satiety over time [17]. Secondly we hypothesized that the addition of this soluble non-viscous fiber to a beverage would decrease energy consumption at subsequent meals and lead to significant declines in calorie intake, body weight, body mass index, and body fat over a period of 9 weeks.

Materials and methods

Subjects

One hundred healthy overweight (BMI 24 to 28 kg/m^2; with 24 as a cut-off point to define overweight in the Chinese setting [18]) adults, 35 to 55 years old (50 men and 50 women) were recruited to participate in this study conducted at a single-center manufacturing plant in the region of Jinhua China. Subjects lived and worked in a manufacturing plant and therefore had similar diets and physical activity levels. Inclusion criteria included BMI of 24 to 28 kg/m^2 with no acute/terminal or chronic diseases and working 7 days a week at the manufacturing plant. Exclusion criteria included current or past use (during the past 3 months) of any dietary fiber or probiotic supplementation, except from food sources; known allergic reaction to wheat products (*e.g.,* gluten intolerance, celiac disease); use of an antibiotic either currently or within the past 3 months; enrollment in another clinical trial within the past 3 months; or contraindications to dietary fiber supplementation, that is, chronic diarrhea, irritable bowel syndrome, chronic use of laxatives, cirrhosis of the liver, inflammatory bowel disease, ulcerative colitis, or Crohn's disease. The study protocol was reviewed by a local institutional review board (Tongji University Medical College Ethics Committee, Shanghai, China) and carried out in accordance with the Declaration of Helsinki. All participants gave written informed consent.

Study design

This study was performed according to a randomized, double-blind, placebo-controlled, single-center, dose-response design. The primary objective of the study was to investigate whether dietary supplementation with NUTRIOSE® at different dosages is associated with an increase of short-term satiety over time [17] and a decrease in caloric intake. The secondary objectives was to investigate whether dietary supplementation with NUTRIOSE® at different dosages is associated with a decrease of the hunger feeling status [17] and a decrease in bodyweight, BMI and body fat.

The study included a two-day run-in period in which all subjects received placebo (250 ml of orange juice) twice daily. They were then randomized by caloric intake and BMI, and assigned to one of five groups of 20 Chinese male and female (1:1) volunteers. Each subject received 250 ml of orange juice twice daily either alone (placebo) or supplemented with NUTRIOSE® at different dosages (8g/day (4g x2), 14g/day (7g x2), 18g/day (9g x2), or 24g/day (12g x2)). All beverages had the same appearance, consistency, smell and taste. At baseline (Day 0) until Week 9, subjects received NUTRIOSE® or placebo orally 3 hours after breakfast (at 10 AM) and 4 hours after lunch (at 4 PM) in the presence of research staff who verified and recorded product consumption. Subjects ate their usual meals in the canteen at the same time (breakfast at 7 AM, lunch at noon, diner at 6:30 PM) every day throughout the study period. Subjects worked from 7 AM to 6:30 PM each day and had no access to additional food during this period. Weight, height, BMI (kg/m^2), and body fat (%, and kg) were measured at days -2, 7, 14, 21, 28, 35, 42, 49, 56, and 63. The daily mean energy intake was assessed during breakfast, lunch and dinner. Short-term satiety was evaluated with a Satiety Questionnaire on days -2, 0, 2, 5, 7, 14 and 21 by using visual analog scales [17]. Hunger feeling status was also evaluated on days -2, 0, 2, 5, 7, 14 and 21 by using a six-point Likert scale [17]. Each administration of placebo or NUTRIOSE® was documented on a Daily Attendance Form, one for each day of the 9-week study period. Any adverse events related to the study product were recorded on an Adverse Event Form.

Study substance

NUTRIOSE® is a purified resistant dextrin (Roquette Frères, Lestrem, France), a glucose polymer processed from wheat or corn starch heated at high temperature and adjusted to a low moisture level in the presence of an acid catalyst [13]. During a highly controlled process of dextrinization, the starch undergoes a degree of hydrolysis followed by repolymerization that converts it to fiber [14]. In addition to the typical starch α-1,4 and α-1,6 glucosidic linkages, the recombination can result in other specific linkages that are not found in starch, including both linear and branched linkages: (α-1,6 and/or β-1,6), (α-1,2 and /or β-1,2), (α-1,3 and /or β-1,3), and β-1,4. This confers to the product a resistance against the action of endogenous glucidolytic enzymes [19] and permits classification of the product among the soluble dietary fibers with a total fiber content of nearly 85%. Approximately 15% of NUTRIOSE® is digested and 75% is fermented in the gastrointestinal tract and the dosage of NUTRIOSE® that does not induce digestive disorders has been estimated at 45 grams per day either on the long and the short term [13-15,19]. NUTRIOSE®, is a mixture of glucose polymers with a fairly narrow range of molecular weight (number average Mol. Wt., Mn = 2,600 g/Mol; weight average Mol. Wt., Mw = 5,000 g/Mol). The degree of polymerization is about 18 [14].

Measurements

Calorie and food intake: The canteen provided weekly menus that indicated the composition of each meal. Based on these menus, the dieticians were able to quantify the nutritional facts such as carbohydrate, fiber, protein, fat and calorie for

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Table 1. Baseline characteristics of subjects by study group.

Characteristic	Placebo	NUTRIOSE® 8g/day	NUTRIOSE® 14g/day	NUTRIOSE® 18g/day	NUTRIOSE® 24g/day
Age (y)	45.0±5.2	44.9±5.4	44.1±5.1	45.5±5.2	44.1±5.2
Sex: Female, n (%)	10 (50)	10 (50)	10 (50)	10 (50)	10 (50)
Sex: Male, n (%)	10 (50)	10 (50)	10 (50)	10 (50)	10 (50)
Weight (kg)	73.06±6.18	73.06±6.74	73.04±7.53	73.03±7.30	73.09±7.36
Height (cm)	167.4±6.0	167.4±7.4	167.3±8.2	167.2±7.6	167.4±7.5
BMI (kg/m²)	26.03±1.13	26.03±1.28	26.04±1.05	26.04±0.82	26.02±1.07
Body fat percent (%)	28.46±3.75	28.45±3.53	28.46±2.89	28.47±3.45	28.47±3.56
Body fat (kg)	20.76±2.97	20.74±2.83	20.69±2.38	20.66±2.35	20.74±2.90

Data are presented as means ± SD, n=20.

each item on the menus through the use of standardized China food composition tables provided by the China Disease Prevention Control Center. All subjects ate at the company canteen 7 days a week and received three meals and two tea breaks daily during the study. Subjects recorded everything they ate and drank throughout the study in a Daily Food Record. In addition, food was weighed before and after each meal with an electronic scale, and a study nurse and/or dietitian calculated the amount consumed, the macronutrient composition and calorie intake for each subject. These parameters were measured daily from day -2 to day 63.

Anthropometric measurements: Before measuring height and body weight, each subject was asked to remove footwear, jewelry, and bulky clothing. Height was measured to the nearest 1 cm on a standardized wall-mounted height board, and weight was electronically calculated to the nearest 0.05 kg. Body fat percentages, body fat mass and fat-free mass were measured by bioelectrical impedance analysis (BIA) using an Omron Model, HBF-306 (Nanshan District, Shenzhen, China).

Randomization and blinding

We randomized 100 subjects to either test or control groups (n=20 volunteers/group) according to body mass index and daily average caloric intake. The blinded randomization sequence was computer-generated by a biostatistician at Sprim USA.

This study was conducted using double-blinding procedures. First, subjects were blinded to the treatment received throughout the trial and the products were of identical look, smell, and flavor. Second, investigators and all involved clinicians were blinded to the treatment allocation throughout the trial. Finally, all study coordinators, clinical monitors, and biostatisticians were blinded to treatment allocation throughout the trial and until after all analyses were completed.

Statistical analysis

The sample size of 100 total subjects (20 per group) was calculated based on an anticipated effect size of 1.0 with each product dose vs. placebo, assuming a two-sided alpha level of 0.05, statistical power of 80%, and a 10% attrition rate.

All statistical analyses were performed using SAS/STAT software (Release 9.2; SAS Institute, Cary, NC, USA). Continuous variables are reported as means ± SD. Cross-sectional comparisons testing the differences among the groups at specific time points were conducted using one-way analysis of variance (ANOVA) and analysis of covariance (ANCOVA). Fisher's method was used to examine multiple comparisons, and Tukey or Scheffe's techniques were used to control for linear contrasts from the null hypothesis. Group comparisons adjusted for least significant difference were used to further evaluation. Statistical significance was set at $P < 0.05$.

Results

Group characteristics

Table 1 shows baseline characteristics of study participants. One hundred subjects (50 males and 50 females) with a mean age range of 44.1±5.1 to 45.5±5.2 years took part in the study. No significant differences were observed in weight (in kilograms), height (in centimeters), BMI (in kilograms per squared meters), or body fat (in percent and kilograms).

Daily total calorie intake

As **Table 2** shows, subjects in the 14 g and 18 g groups consumed significantly less ($P < 0.05$ and 0.01) total energy from week 7 compared to placebo. For the 24 g fiber group a decrease of the daily total caloric intake is observed compared to placebo at weeks 5, 6, 7, 8 and 9 ($P < 0.05$ and 0.01).

In a comparison of time effects within the same treatment group, significant differences compared to baseline were seen from week 2 for the 24g fiber group ($P = 0.0425$), from week 4 for the 14g and 18g fiber groups (respectively $P = 0.0006$ and 0.0331). The decrease of the daily total calorie intake over the study period is progressive. Between baseline and week 9, these reductions are -38 kcal/day for the 8g group, -292 kcal/day for the 14g group, -336 kcal/day for the 18g group and -394 kcal/day for the 24 g group.

Body weight, BMI and body fat

Mean values for body weight (**Table 3**), BMI (**Table 4**), and body

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Table 2. Total daily calorie intake in kcal.

	Placebo	NUTRIOSE® 8g/day	NUTRIOSE® 14g/day	NUTRIOSE® 18g/day	NUTRIOSE® 24g/day	p-value*
Week 0	2705 ± 341	2705 ± 337	2685 ± 326	2716 ± 341	2736 ± 359	0.9932
Week 1	2711 ± 302	2706 ± 259	2695 ± 250	2695 ± 305	2690 ± 266	0.9992
Week 2	2730 ± 281	2704 ± 256	2669 ± 230	2650 ± 288	2612 ± 198‖	0.6184
Week 3	2715 ± 299	2700 ± 252	2623 ± 230	2615 ± 285	2569 ± 257‖	0.3773
Week 4	2717 ±299	2696 ± 248	2581 ± 242‖	2570 ± 277‖	2529 ± 218‖	0.0911
Week 5†	2722 ± 292	2692 ± 245	2533 ± 228‖	2526 ± 221‖	2494 ± 236‖	0.0082
Week 6†	2728 ± 299	2690 ± 245	2512 ± 277‖	2513 ± 232‖	2475 ± 259‖	0.0070
Week 7‡	2719 ± 306	2680 ± 248	2466 ± 225‖	2469 ± 221‖	2428 ± 229‖	0.0003
Week 8§	2719 ± 305	2675 ± 244	2438 ± 171‖	2438 ± 167‖	2384 ± 160‖	0.0001
Week 9§	2726 ± 303	2667 ± 244	2393 ± 130‖	2380 ± 141‖	2342 ± 103‖	0.0000

Data are presented as means ± SD, n=20.
* Parametric ANOVA, overall p-value testing that at least one mean differs from another.
† Placebo vs. 24 is significant at $p < 0.05$, Tukey test.
‡ Placebo vs. 24 is significant at $p < 0.01$; placebo vs. 18, placebo vs. 14, and 8 vs. 24 are significant at $p < 0.05$, Tukey test.
§ Placebo vs. 24, placebo vs. 18, placebo vs. 14, 8 vs. 24, 8 vs. 18, and 8 vs. 14 are significant at $p < 0.01$, Tukey test.
‖ $p < 0.05$ comparing time effects within the same treatment group.

Table 3. Mean body weight (in kg) values by study group over the study period.

	Placebo	NUTRIOSE® 8g/day	NUTRIOSE® 14g/day	NUTRIOSE® 18g/day	NUTRIOSE® 24g/day
Baseline	73.06±6.18	73.06±6.74	73.04±7.53	73.03±7.30	73.09±7.36
Week 1	73.07±6.18	73.05±6.74	73.00±7.54	72.99±7.29	72.99±7.36
Week 2	73.10±6.17	73.05±6.72	72.95±7.54	72.93±7.29	72.88±7.34
Week 3	73.12±6.19	73.03±6.70	72.90±7.52	72.85±7.31	72.78±7.35
Week 4	73.13±6.18	73.03±6.70	72.85±7.48	72.78±7.30	72.68±7.35
Week 5	73.18±6.28	72.99±6.71	72.79±7.49	72.68±7.31	72.59±7.35
Week 6	73.20±6.21	72.98±6.87	72.74±7.45	72.64±7.31	72.45±7.37
Week 7	73.20±6.19	72.95±6.86	72.70±7.45	72.56±7.35	72.35±7.38
Week 8	73.22±6.19	72.95±6.87	72.67±7.45	72.48±7.55	72.11±7.57
Week 9	73.25±6.18	72.94±6.89	72.62±7.45	72.41±7.54	72.03±7.58
Change at Week 9 relative to baseline	+0.19±0.18	-0.12±0.16	-0.42±0.18	-0.62±0.16	-1.06±0.18
p-value*	0.67	0.65	**0.04**	**0.03**	**0.02**

Data are presented as means ± SD, n=20.
* P values are for differences between week 9 and baseline.

fat (**Table 5**) declined steadily for all fiber groups from baseline throughout the study; mean values for the placebo group remained unchanged or increased slightly. As shown in Tables 3 and 4, the decreases in mean values for body weight and BMI between baseline and week 9 were statistically significant ($P < 0.05$) for the 14 g, 18 g and 24 g fiber groups. Declines in mean body weight between baseline and week 9 in the 24, 18, and 14 g groups were 1.06 ± 0.18 kg ($P = 0.02$); 0.62 ± 0.16 kg ($P = 0.03$); 0.42 ± 0.18 kg ($P = 0.04$), respectively. The decline in the 8 g group of 0.12 ± 0.16 kg was not significant. Between baseline and week 9, mean body weight in the placebo group increased 0.19 ± 0.18 kg, but the amount was not significant. **Table 4** shows that BMI in the 24 g group fell by 0.41 ± 0.04 kg/m^2 ($P = 0.03$) between baseline and week 9; during the same period for the 18 and 14 g groups, the declines were 0.21 ± 0.04 ($P = 0.03$) and 0.15 ± 0.03 ($P = 0.04$). The decrease for the 8g group and the increase in baseline BMI for placebo were not significant.

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Table 4. Mean BMI (in kg/m2) of study groups over the study period.

	Placebo	NUTRIOSE® 8g/day	NUTRIOSE® 14g/day	NUTRIOSE® 18g/day	NUTRIOSE® 24g/day
Baseline	26.03±1.13	26.03±1.28	26.04±1.05	26.04±0.82	26.02±1.07
Week 1	26.04±1.13	26.03±1.27	26.03±1.04	26.03±0.83	25.99±1.08
Week 2	26.05±1.13	26.03±1.27	26.01±1.04	26.01±0.84	25.95±1.07
Week 3	26.05±1.13	26.02±1.27	25.99±1.03	25.98±0.85	25.91±1.07
Week 4	26.06±1.13	26.02±1.27	25.98±1.03	25.95±0.85	25.88±1.07
Week 5	26.06±1.12	26.01±1.27	25.95±1.03	25.92±0.85	25.84±1.07
Week 6	26.07±1.07	26.00±1.31	25.94±1.03	25.90±0.86	25.80±1.07
Week 7	26.07±1.07	25.98±1.29	25.92±1.02	25.87±0.87	25.76±1.08
Week 8	26.08±1.07	25.98±1.30	25.91±1.01	25.85±0.89	25.74±1.09
Week 9	26.09±1.07	25.98±1.31	25.89±1.00	25.83±0.88	25.71±1.09
Change at Week 9 relative to baseline	+0.06±0.03	-0.05±0.04	-0.15±0.03	-0.21±0.04	-0.41±0.04
p-value*	0.73	0.65	**0.04**	**0.03**	**0.03**

Data are presented as means ± SD, n=20.
* P values are for differences between week 9 and baseline.

Table 5. Mean body fat (in %) of study groups over the study period.

	Placebo	NUTRIOSE® 8g/day	NUTRIOSE® 14g/day	NUTRIOSE® 18g/day	NUTRIOSE® 24g/day
Baseline	28.46±3.75	28.45±3.53	28.46±2.89	28.47±3.45	28.47±3.56
Week 1	28.46±3.75	28.45±3.53	28.45±2.89	28.45±3.45	28.45±3.56
Week 2	28.47±3.75	28.45±3.53	28.44±2.89	28.44±3.45	28.43±3.56
Week 3	28.47±3.75	28.44±3.53	28.43±2.89	28.42±3.45	28.40±3.56
Week 4	28.47±3.75	28.44±3.53	28.42±2.89	28.40±3.45	28.38±3.56
Week 5	28.49±3.91	28.44±3.53	28.41±2.89	28.39±3.45	28.35±3.56
Week 6	28.49±3.91	28.44±3.62	28.40±2.89	28.38±3.45	28.32±3.56
Week 7	28.50±3.91	28.43±3.62	28.39±2.90	28.37±3.45	28.30±3.56
Week 8	28.50±3.91	28.43±3.62	28.38±2.90	28.36±3.55	28.27±3.65
Week 9	28.50±3.91	28.42±3.62	28.37±2.90	28.35±3.54	28.25±3.66
Change at Week 9 relative to baseline	+0.04±0.05	-0.03±0.06	-0.09±0.05	-0.12±0.05	-0.22±0.04
p-value*	0.85	0.83	0.82	**0.04**	**0.04**

Data are presented as means ± SD, n=20.
* P values are for differences between week 9 and baseline.

As shown in **Table 5**, the decrease in mean values for body fat between baseline and week 9 was statistically significant ($P < 0.05$) for the 18g and 24g fiber groups. Mean body fat in the 24 g group decreased by 0.22 ± 0.04 % ($P = 0.04$) between baseline and week 9. The respective declines in body fat for the 18, 14, and 8 g groups are shown in **Table 5**. The increase in mean body fat between baseline and week 9 in the placebo group was 0.04 ± 0.05 % (P = NS). The 8 g fiber group showed the least decrease in body fat; the 24 g group, the most.

The effects observed in body weight, BMI and body fat are correlated to the ingested dose of fiber; the significance increase with the dosage.

Discussion

The aim of this study was to demonstrate the effect of a dextrin on energy intake, body weight, BMI and body fat in overweight Chinese adults by comparing four different doses of NUTRIOSE® with placebo. Our results show decreases in many variables, with the lowest response in the 8 g group and the highest in the 24 g group, suggesting a dose-response relationship. Other results obtained in this study, suggest that dietary supplementation with NUTRIOSE® decreases significantly

hunger feeling and increases significantly short-term satiety over time with time- and dose-responses relationship [17]. Indeed, some statistical differences appear for the group 8g/day from day 5, and from day 0 for the groups 14g, 18g and 24g/day. The hunger feeling status decreases significantly from day 5 to the end of the evaluation for the group 24g and from day 7 for the groups 14g and 18g. These results suggest a strong link between satiety and weight management with NUTRIOSE® supplementation.

Fiber includes a wide range of compounds; not all are equally effective at affecting satiety [10,20-24]. Viscous fiber, such as guar gum, oat bran, and psyllium, are generally more effective, although insoluble fibers that survive gut transit, such as wheat bran and cellulose, are also known to alter satiety [10]. Resistant starch, a fermentable carbohydrate, has properties similar to dietary fiber [25], and therefore, could also affect satiety in weight regulation [20].

A review by Howarth *et al.,* [26] summarized the effects of dietary fiber on hunger, satiety, energy intake, and body weight. When energy intake is *ad libitum*, mean values for published studies indicate that consumption of an additional 14 g/d of fiber for more than 2 days is associated with a 10% decrease in energy intake and body weight loss of 1.9 kg over 3.8 months but the effect is even more pronounced among obese individuals [26]. In the longitudinal C*ARDIA* study, fiber had a strong negative association with 10 year weight gain, whereas fat had no association [27]. Those in the lowest quintile of fiber intake (<5 g/1,000 kcal/d) gained an average of 8 lbs more than those in the highest quintile (>12 g/1,000 kcal/d). Very few studies evaluating the effects of fiber consumption have measured body fat in addition to body weight [8]. Yet, in a recent prospective cohort study, Tucker *et al.,* [8] measured diet using 7-day weighed food records and assessed body fat. Outcomes showed that for each 1g increase in total fiber consumed, weight decreased by 0.25 kg ($P < 0.01$) and fat decreased by a 0.25 percentage point ($P < 0.01$). Cross-sectional observational studies also have found an inverse association between fiber intake, body weight [28] and body fat [29,30]. In a previous study, NUTRIOSE® supplementation for 12 weeks at 34g/day has shown positive results in body composition improvements resulting in a decrease of body weight, energy intake and hunger feeling in overweight Chinese men [16]. In addition, this study has demonstrated an improvement in determinants of metabolic syndrome with increases in adiponectin and reductions in glucose, insulin, homeostasis model assessment-estimated insulin resistance, glycosylated hemoglobin and glycated albumin [31].

These outcomes may firstly be the result of hypoglycemic and hypoinsulinemic effects, and low calorie values of fiber. Postprandial blood glucose and insulin responses to dietary starch are directly related to the rate of starch digestion [32]. Several researchers have reported that low glycemic index (GI) foods enhance higher satiety responses than high glycemic foods. 15% of NUTRIOSE® is slowly digested in the small intestine [13], which induces a low glycemic response (glucose response = 25) and a low insulinemic response (IR = 13) [33]. Because low-GI foods are characterized by a slower rate of digestion and absorption, prolonged feedback (likely through satiety signals) to the hunger/satiety center in the brain is probably due to continuous stimulation of nutrient receptors in the gastrointestinal tract. Secondly, research also suggests that the biologic actions of fiber in the large intestine may also have implications for body-weight regulation [34]. Fiber and certain types of starch are resistant to enzymatic digestion in the small intestine and are therefore susceptible to fermentation by bacteria in the colon. The products of this fermentation process, including short-chain fatty acids as butyrate, and propionate enter the portal circulation, and may affect glucose homeostasis in a variety of ways [34-36]. Short-chain fatty acids seem to decrease hepatic output of glucose and circulating concentrations of free fatty acids [34,35] and stimulate secretion of glucagon-like peptide-1 and in turn, induce a regulation in satiety [34]. It is also in line with more recent studies demonstrating the potential role of butyrate on the liberation of some gut peptides such as GLP-1 and PYY, secreted in response to ingested nutrients and playing an important role in the control of energy homeostasis [37]. Additionally, Cani *et al.,* observed that a 2-week fructan supplementation induced an increase in gut microbial fermentation, which was associated with an increase in GLP-1 and PYY concentrations and with a reduction in hunger sensation [38]. Presumably, this mechanism of action reduces hunger and leads to a lower daily energy intake by stimulating the release of gut peptides due to colonic fermentation. NUTRIOSE® has demonstrated a high rate of fermentation in rats by the production of short-chain fatty acids [13,39] suggesting a potential role in some gut peptides secretion which may lead to a regulation of satiety and caloric intakes. In addition, it has been shown that the intestinal fermentations of low digestible carbohydrates can induce a 1 to 2% increase of energy expenditures due to peristaltism alteration and increase of the gut mucosa [40].

The current study was not without limitations. The cohort was homogeneous, which limits the ability to generalize findings to a more diverse population using novel resistant dextrins like NUTRIOSE® on weight control because the population selected in this study lived in highly standardized environment. In addition, the dosage of glucose, insulin and gut peptides would have been of a great interest to go deeper in the mechanism of action of NUTRIOSE®.

Conclusion

The study indicates that a novel resistant dextrin can reduce energy intake, body weight, BMI, and body fat in a dose-response manner over a 9-week period. These results confirm the data obtained in a previous study [16,30], suggesting a role for NUTRIOSE® in weight management. Studies investigating

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mechanisms of actions, such as hormonal and colonic effects, are required to explain NUTRIOSE®'s role in weight control.

Competing interests

Roquette Frères (Lestrem, France) provided financial support for this clinical trial and participated in manuscript development. SPRIM Advanced Life Sciences (San Francisco, CA, USA) managed the implementation of the study. NutraSource (Clarksville, MD, USA) helped in manuscript development.
The authors declare that they have no competing interests.

Authors' contributions

LGD, MP, CR developed the protocol. CR, LEM managed study planning and analysis. LGD, DW, LEM, SC developed the manuscript. Final manuscript was read and approved by all the authors.

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